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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/254,966	03/16/99	CORREA R	MO-5092/LEA

HM12/0118

BAYER CORPORATION
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EXAMINER	
WINKLER,U	
ART UNIT	**PAPER NUMBER**
1645	4

DATE MAILED: 01/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/254,966	CORREA ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *16 March 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 13-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 13-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☒ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☒ Other: *Sequence error report* .

DETAILED ACTION

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim 6 is objected to because of the following informalities: grammar, the claim should read "peptides as defined in claim 1". Appropriate correction is required.

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,4,5,13,14 and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is not clear what is meant by "based on". Amending this to "comprising" would clarify the claim.

Claim1 is not clear what is meant by "part-sequence". "Part- sequence" is not defined in the specification in such a way that a person skilled in the art would know the metes and bounds of a "part-sequence". As written, it is not clear what the claimed peptides correspond to.

Claim 1 is not clear what is meant by "immunoreactivity". It is also not clear whether B or T cell activity or both is encompassed by the claim.

Claims 4,5,13 and 14 are not clear whether the DNA sequences or the protein sequences encompassing the non-structural proteins L/L, 2B, 2C, 3A, 3B, 3D are claimed.

The term "characterized in that" renders claims 4,5,13 and 14 indefinite. It is unclear if Applicant intends to claim an improvement of an old method. If so, Applicant has not defined what is old. The phrase is objectionable as it obscures what Applicant intends as his invention by not clearly defining if Applicant is claiming improvements.

Claims 24-27 are vague and indefinite as it is unclear to what the claim is directed: a system can be a method or a composition. If the claims are directed to a method, they lack positive method steps.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 24-27 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The word "system" does not meet the criteria of 35 USC 101 as it can be a method or composition. Therefore, it is not one of the statutory classes of invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamorano et al. (Virology 1995) and Rodriguez et al. (Arch. Virol. 1994).

The instant invention is directed to formulating a peptide-based vaccine against FMDV. The peptides are chosen from the non-structural protein sequences of FMDV. The peptides can be synthesized or made by using recombinant DNA technology.

Zamorano et al. teach that peptide-based vaccines can elicit B- and T- cell immune responses. The peptides in the reference are 10 amino acids in length and they correspond to amino acid residues of the VP1 structural protein sequences of FMDV. Zamorano et al. also teach that the peptides in the test vaccines can be used with or without a coupled protein carrier. Zamorano et al. do not teach making peptides against the non-structural proteins of FMDV.

Rodriguez et al. teach that animals that have been immunized with killed whole FMDV vaccine produce a different antibody profile when compared to animals that have recovered from an active viral infection. Animals that have recovered from an active infection are more resistant to reinfection when challenged with the same viral strain as compared to animals that have been vaccinated. The major differences between vaccinated and convalescent animals are their antibody profiles. Convalescent animals produce antibodies against the non-structural proteins (see Fig 3). To test serum samples, Rodriguez et al. made peptides of the non-structural proteins

using recombinant DNA technology. Rodriguez et al. does not teach making a peptide based vaccine.

While peptide based vaccines for FMDV have been directed at the structural proteins, the vaccines are not as successful as the killed whole virus vaccines. One would have been motivated at the time the invention was filed to produce a peptide-based vaccine that is able to elicit the same immune profile as that of convalescent animal by directing peptides against the non-structural proteins. Some of the advantages of peptide based vaccines are that they are chemically defined, stable, and do not contain a potential infectious agents. Therefore, the present invention is obvious in view of Zamorano et al. and Rodriguez et al..

Claims 1-8 and 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamorano et al. (Virology 1995) and Rodriguez et al. (Arch. Virol. 1994) in view of Morgan et al. (Am. J. Vet. Res. 1990).

The instant invention is directed to formulating a peptide-based vaccine against FMDV and using it to immunize swine and cattle. The peptides are chosen from the non-structural protein sequences of FMDV. The relevance of Zamorano et al. and Rodriguez et al. has been discussed above. They do not teach a protocol of vaccinating swine and cattle with a peptide based vaccine. Morgan et al. teach administering a peptide vaccines against FMDV in pigs and cattle. Morgan et al. does not teach using a peptide vaccine against non-structural proteins of FMDV.

The economic impact of FMDV on the agricultural industry is well established. One would be motivated to produce an effective vaccine against the disease that poses little problem for large-scale production. Formulating the non-structural peptides into a veterinary acceptable carrier as taught by Morgan et al. would be an obvious step for using the teachings of Zamorano et al. and Rodriguez et al.. Therefore, the instant invention is obvious over Zamorano et al. and Rodriguez et al. in view of Morgan et al..

Claims 1-8 and 13-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamorano et al. (Virology 1995) and Rodriguez et al. (Arch. Virol. 1994) in view of Lubroth et al. (Vaccine 1996).

The instant invention is directed to establishing a method by which to distinguish between vaccinated animals and convalescent animals. The relevance of Zamorano et al. and Rodriguez et al. has been discussed above. They teach how to distinguish between vaccinated and convalescent swine, but they do not teach how to distinguish between vaccinated and convalescent cattle. Lubroth et al. teaches a method of distinguishing between vaccinated and convalescent cattle.

The economic impact of FMDV on the agricultural industry is well established. One would be motivated to distinguish between vaccinated and convalescent animals in order to prevent the spread of the disease by animals that may be non-symptomatic carriers by using the techniques taught by Zamorano et al. and Rodriguez et al. for cattle as taught by Lubroth et al.

Therefore, the instant invention is obvious over Zamorano et al. and Rodriguez et al. in view of Lubroth et al..

The following references are cited as being relevant:

Schaller et al. US No. 4605512.

Francis et al., "Immune response to uncoupled peptides of foot and mouth disease virus." Immunology Vol. 61 (1987), p.1-6.

Zamorano et al., "Recognition of B and T cell epitopes by cattle immunized with a synthetic peptide containing the major immunogenic site of VP1 FMDV 01 Campos." Virology Vol 201 (1994) p. 383-387.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached on 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned are 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

UW

Ulrike Winkler, Ph.D.
January 12, 2000

Jeffrey Stucker

JEFFREY STUCKER
PRIMARY EXAMINER

Application No.: 09/254,966

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: _____

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE